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## (54) Hygienic protection devices for medical apparatus

(57) A sheath of flexible, substantially liquid-impermeable material is shaped and dimensioned to fit over an exposed end portion of medical apparatus to be inserted into a body cavity. The sheath is secured in place either by its own inherent elasticity, or by a layer of adhesive. The sheath, which may be either disposable or resterilisable, may be used over the end portion of a clinical thermometer, or of a dental composite hardening device, the latter comprising a source of visible or ultraviolet light, an operating tip or extension arranged to direct the light at a tooth cavity, and an optical connection between the source and the tip or extension, whereby the sheath prevents or reduces possible contamination of the tip or extension by body fluids.

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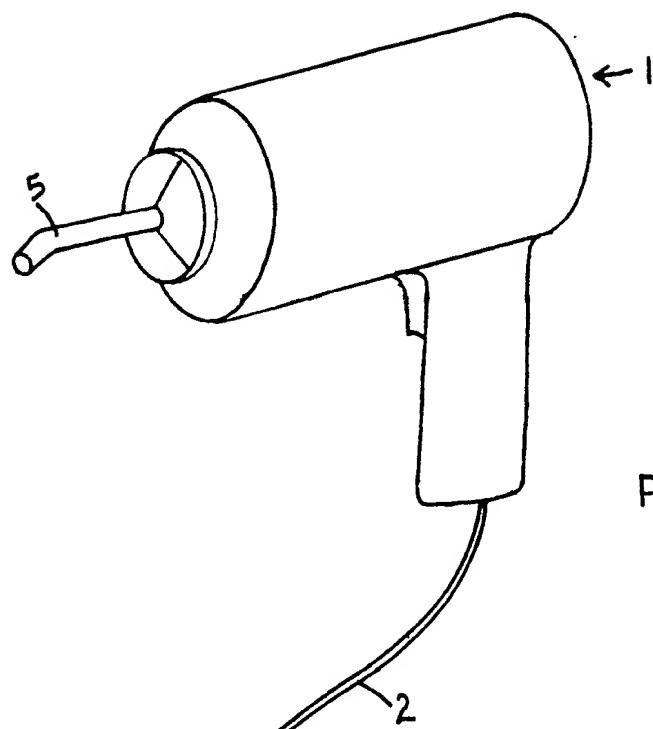


Fig 1

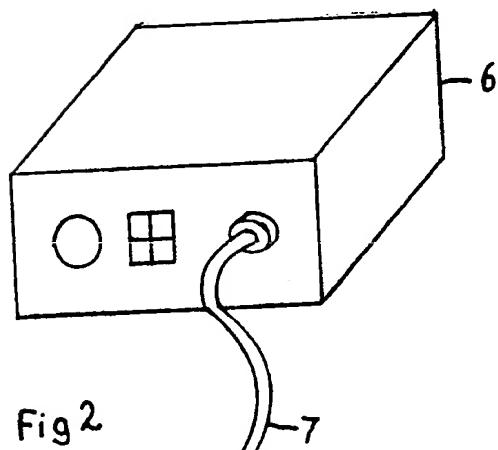
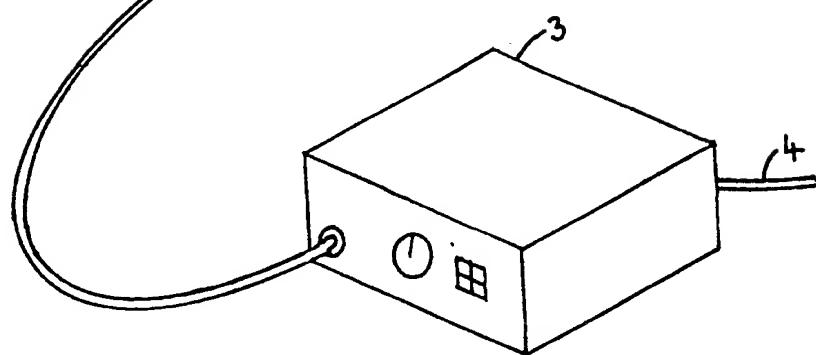


Fig 2

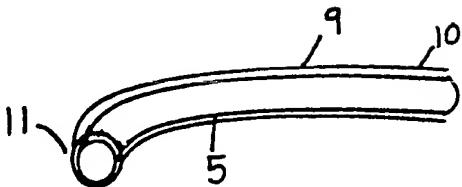


Fig 3



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Fig 4

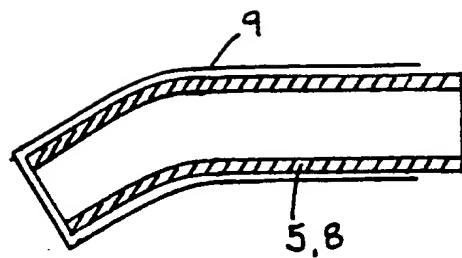
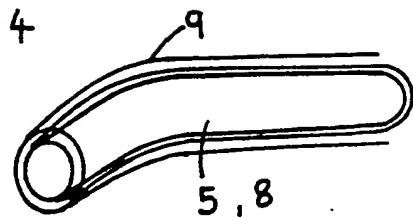


Fig 5

Fig 6

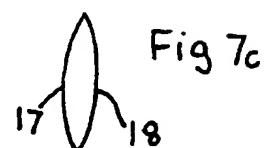
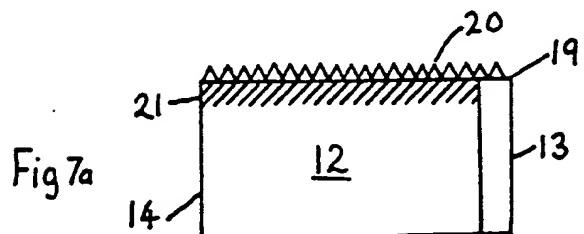
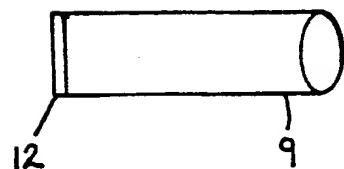


Fig 7a

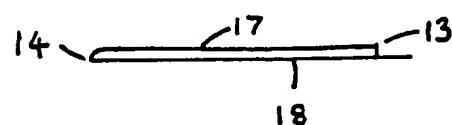


Fig 7b

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Hygienic Protection Devices

This invention relates to the hygienic protection of medical apparatus (including dental apparatus) to be inserted into a body cavity.

It is frequently required to insert medical apparatus into a body cavity, such as the mouth, alimentary canal or rectum. Examples of such apparatus include dental apparatus (such as apparatus used in filling of dental cavities), clinical thermometers and the like.

In the filling of dental cavities in teeth it is known to use pastes, often called composites, comprising resins and fillers, and optionally accelerators and other hardening adjuvants. Such composites may comprise two pastes which harden when mixed together, sometimes over a prolonged period; resins without fillers have also been used because of their ability to adhere to a cleaned and etched tooth surface.

Two separate systems have been developed to enable a dentist to have greater control over the setting time of the filling material. One system uses material which is curable by ultra-violet light, while another system uses material which is curable by visible light. The source of ultra-violet light may be a hand-held gun with a tip or extension which can be aimed at the filled cavity; the source of visible light may be such a gun or an operating device with a flexible fibre-optic cable having a tip which can be directed at the cavity filling. These tools have also been used to trans-illuminate suspected carious lesions.

For further details of such systems reference may be made to papers in The British Dental Journal of 24th March 1984, entitled "Characteristics of Visible-Light-Activated Composite Systems", and of 24th January 1987 entitled "Variations in Performance of Curing Light Units by Determination of Composite Resin Setting Time".

A problem with both systems is that the tip or extension, whether it be connected directly to a light source or to a fibre-optic cable, is exposed to possible contamination by micro-organisms and also by the filler materials. Because of the delicate nature of the tips it is often not convenient or possible to use conventional cleaning and sterilising equipment.

The present invention aims to provide means for reducing or obviating the above-mentioned problem.

In accordance with one aspect of the invention there is provided a sheath of flexible substantially liquid-impermeable material, said sheath having an open end and a closed end and being shaped and dimensioned to fit over an exposed elongate end portion of medical apparatus to be inserted into a body cavity and to provide a liquid barrier between said end portion and said body cavity; said sheath being provided with means for securing it in place over said end portion.

The sheath thereby provides a barrier to substantially prevent contamination of the end portion of the medical apparatus either by chemicals or by micro-organisms and thereby reduces the risk of cross-infection. In a first embodiment of the invention, the sheath is disposable, while in a further embodiment, the sheath may be reusable, and sterilisable prior to reuse.

In accordance with another aspect of the invention, there is provided medical apparatus to be inserted into a body cavity, which comprises an exposed elongate end portion having fitted thereover a sheath according to the

invention so as to provide a liquid barrier between said end portion and said body cavity, said sheath being held in place by said securing means. The end portion just described is preferably of translucent or transparent glass or plastics and arranged for illumination of the body cavity, or selected parts thereof, through the sheath.

In one embodiment of the invention, the sheath is of an elastic (or elastomeric), liquid-impervious material such that the sheath is a snug fit on the tip to thereby prevent contamination of the end portion; in this case, the means for securing the sheath in place is the sheath's inherent property of elasticity. In this embodiment, the sheath may be of dipped rubber, of the type conventionally used for the manufacture of condoms or the like.

In a further embodiment of the invention, the sheath may be a relatively more loose fit and provided with securing means such as a layer of adhesive or an externally applied clamp, peg or the like.

The layer of adhesive may be on an internal surface of the sheath (in which case, the sheath would be bonded thereby to the tip or extension), or on the external surface (in which case, the sheath may be folded or rolled in such a way that spaced portions of the sheath are bonded to one another around the tip or extension).

Such adhesive-coated sheaths may be provided in the form of a continuous roll or stack, with means for separating individual sheaths from the roll; such separation means may, for example, comprise a line of perforations between adjacent sheaths. Seen from another aspect, therefore, the present invention comprises a roll or stack comprising a multiplicity of adhesive-coated sheaths according to the invention. Such a roll or stack may be provided in a container for dispensing individual sheaths.

The material of the sheath is preferably such that it may comprise an integral self-supporting body which is sufficiently transparent (or translucent) to permit the transmission of sufficient light through its end, for example, to permit curing of a dental composite material.

In this embodiment of the invention, the sheath may be of a synthetic plastics or elastomeric material, such as polyethylene, polyurethane or the like. For example, the sheath may be formed of sheet material bonded to itself to form a body with one closed end, one open end and a continuous side wall portion. The sheath may, in some embodiments, be inwardly tapering from the open end thereof.

Whilst the sheaths according to the invention are particularly suitable for light-transmitting guns for dental use, they could also be used over other types of dental instruments or probes, for example, a clinical thermometer or other surgical instruments which might be used by a practitioner, particularly on home visits.

The present invention further comprises a method of reconditioning medical apparatus according to the invention, which comprises removing a sheath as described above from the exposed end portion of the apparatus, and either sterilising said sheath and refitting said sterilised sheath over said end portion, or fitting a further sterile sheath according to the invention over said end portion.

In this embodiment of the invention, when the sheath is sterilised, it is preferably fitted over a shaped former and subjected to steam, which is preferably channelled both over the inner and outer surfaces of the sheath (the channelling over the inner surface being achieved by channelling the steam around, or through, the former). Alternatively, other means of sterilisation (such as gamma-radiation) may also be employed.

Embodiments of the invention will now be described, by way of example, with reference to the accompanying drawings, in which:-

Figure 1 is a schematic representation of a known form of dental light unit;

Figure 2 is a schematic representation of a known type of fibre-optic unit;

Figure 3 is a detail view of the tip of one of such units together with a sheath according to the invention;

Figure 4 is a detail view showing the sheath of Figure 3 attached to the tip;

Figure 5 is a sectional view showing the sheath in place; and

Figures 6 and 7a to 7c show further forms of sheath according to the invention.

Referring to Figure 1, a light-emitting unit of known type comprises a hand-held gun 1 containing a light-source connected via a power supply 2 to a control box 3 (which is itself provided with a power supply 4). The control box acts as both a transformer and timer to control the time of emission of the light from the gun 1. The gun 1 has a tip or extension 5 which is a light guide, the end of which is inserted into a patient's mouth. Referring to Figure 2, the unit shown comprise a light source/timer 6 connected via fibre optic light guide 7 to an operating extension 8.

Figure 3 shows a disposable sheath 9 of elastomeric material in accordance with one embodiment of the present invention, which sheath has an open end 10 and a closed end 11, and fits over the tip 5 of the gun of Figure 1 or the extension 8 of the light guide 7 of Figure 2 to prevent or reduce the possibility of cross-infection from one patient to another. The sheath is of a material which is substantially impervious to liquids, particularly saliva and blood.

Figures 4 and 5 show the sheath 9 in position over the tip or extension 5,8 of the light-emitting device.

Figure 6 shows another embodiment of the invention in which the flexible sheath 9 has attached to its end a translucent lens 12, which is preferably hard and which provides good protection for the end of the tip. The end portion of the sheath may be shaped to better direct the light to the required location.

Figures 7a to 7c show, respectively plan, side elevation and end elevations of another embodiment of the invention, in which the sheath 13 has an open end 14 and a closed end 15, and, optionally, a longitudinal weld line (not shown). One face 17 is shorter than the other face 18 in order to aid opening of the sheath. The other face 18 has a longitudinal flange 19 with a torn edge 20 (where the sheath has been torn from a roll). On the outer surface of the sheath is a longitudinally extending adhesive stripe 21; in use, when the sheath is fitted over the tip, extension or the like, the excess material can be pinched into a flap and rolled around the tip or extension such that the outer surface can be bonded to a spaced portion of the surface by means of the adhesive stripe.

Although described above in relation to dental equipment, sheaths in accordance with the invention could be used for other purposes, for example, over a clinical thermometer or other type of probe or surgical instrument, particularly instruments which are difficult or inconvenient to sterilise.

CLAIMS:

1. A sheath of substantially liquid-impermeable, flexible material, said sheath having an open end and a closed end and being shaped and dimensioned to fit over an exposed elongate end portion of medical apparatus to be inserted into a body cavity and to provide a liquid barrier between said end portion and said body cavity; said sheath being provided with means for securing it in place over said end portion.
2. A sheath according to claim 1, which is inwardly tapering from said open end.
3. A sheath according to claim 1 or 2, wherein said material is of an elastomeric nature and said sheath is such that it is a snug fit on said end portion.
4. A sheath according to claim 3, wherein said material comprises dipped rubber.
5. A sheath according to claim 1 or 2, which is a relatively loose fit on said end portion and wherein said securing means comprises a layer of adhesive on said material.
6. A sheath according to claim 5, which is adapted to be folded or rolled around said end portion with spaced portions of said sheath bonded to one another by said adhesive layer.
7. A sheath according to any of claims 1 to 6, which is sufficiently transparent (or translucent) to permit the transmission of sufficient light through said closed end to effect curing of a dental composite material.

8. A sheath according to claim 7, which is formed of sheet material bonded to itself to form a body comprising said closed end, said open end, and a continuous side wall.
9. A roll or stack comprising a multiplicity of sheaths according to claim 5 or 6, and means for permitting separation of said sheaths from one another.
10. Medical apparatus to be inserted into a body cavity, which comprises an exposed elongate end portion having fitted thereover a sheath according to any of claims 1 to 8 so as to provide a liquid barrier between said end portion and said body cavity, said sheath being held in place by said securing means.
11. Medical apparatus according to claim 10, wherein said end portion comprises transparent or translucent glass or plastics material.
12. Medical apparatus according to claim 10 or 11 in which said sheath is as defined in claim 7 or 8, which apparatus is a hand-holdable light-emitting dental device for effecting curing of dental composites or illumination of carious lesions, wherein said apparatus comprises a source of visible or ultraviolet light; said end portion, which is arranged to direct said light at a tooth cavity; and means for making an optical connection between said source and said end portion.
13. A method of reconditioning medical apparatus according to any of claims 10 to 12, which comprises removing said sheath from said end portion and either sterilising said sheath and refitting said sterilised sheath over said end portion, or fitting a further sterile sheath according to any of claims 1 to 8 over said end portion.

14. A sheath for an exposed elongate end portion of medical apparatus to be inserted into a body cavity, substantially as described herein with reference to Figures 4 to 6 or 7a to 7c of the accompanying drawings.
15. Medical apparatus to be inserted into a body cavity, substantially as described herein with reference to Figures 3 to 6 or 7a to 7c of the accompanying drawings.
16. A method according to claim 13, substantially as described herein.